EPA

MRID

NUMBER

42279.00

ISK·BIOTECH

September 15, 1993

429279-00

Ms. Cynthia Giles-Parker (PM-22)
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Desk (APPL-0097)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Giles-Parker:

Subject: OMNI™ – Application for Registration (5/15/92)
EPA File Symbol No. 50534-ENG
RESPONSE TO EPA'S LETTER DATED APRIL 26, 1993

SUBMISSION OF ADDITIONAL INFORMATION &
REQUEST TO RECONSIDER STUDY (MRID #42325606)
Proposed Labeling is Amended to Comply with
Worker Protection Standard

EXPEDITED REVIEW REQUESTED

Submitted herewith in the ADMINISTRATIVE MATERIALS is one (1) Application for Pesticide Registration and five (5) copies of proposed labeling. Also included herewith are three (3) separately-bound copies of the following document in response to EPA's letter dated April 26, 1993:

Data Req't	Document Number	Name of Document
81-3	FW-93-RPB-005-001 429279 01	Response to Reviewers comments re the following study: ACUTE (FOUR-HOUR) INHALATION TOXICITY (LC_{50}) STUDY IN RATS WITH ASC-66792-X-0104 (MRID #42325606; Doc. No. 3594-90-0172-TX-002)

The Senior Toxicologist at Huntingdon Research Centre Ltd. has provided a document with information which responds to reasons given for determination that ISK Biotech's previously submitted study (MRID #42325606; Doc. No. 3594-90-0172-TX-002) did not satisfy the guidelines for an acute inhalation toxicity study with OMNI. He has provided additional information and an evaluation of the conduct of that study and has concluded, even though the test substance was difficult to aerosolize, that >25% of the particles were less than 4 microns and that it was possible to assign a toxicity category of Category II with an acute LC_{50} of 0.46 mg/l for female rates. He stated that the "value for males or for the sexes combined would be higher than 0.46 mg/l."

Based on the additional information provided by Dr. Hardy and his evaluation of the scientific integrity of the study, we ask that the Agency reconsider this study and upgrade it to "core", satisfying the requirements of Guideline No. 81-3. It his determination that this study supports the classification of OMNI as toxicity Category II for inhalation.

Ms. Cynthia Giles-Parker (PM-22)
September 15, 1993

Appended (for easy review) to the current document are copies of EPA's letter dated April 26, 1993, EPA's review dated April 9, 1993 and Clement International Corporation's DATA EVALUATION REPORT for subject study.

Proposed labeling submitted herewith makes changes directed by the Agency's April 26, 1993 letter; however, since this product must also comply with the Worker Protection Standard (WPS), some of the statements noted in the Agency's letter are affected by the WPS. Thus, we are submitting labeling which we believe to correctly incorporate necessary statements to comply with the WPS.

Although your letter said that "Do not take internally" should be deleted because it is unnecessary, it is ISK Biotech's belief that, even though it may seem to be an unnecessary statement, it should stay on the label to insure, for legal reasons, that the label offers clear warning not to take this product internally.

Sincerely yours,

Ralph P. Burton

Ralph P. Burton
Manager, Product Registrations

2082